IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT	FILED
	U.S. COURT OF APPEAL
No. 06-16003	ELEVENTH CIRCUIT JUNE 30, 2008
	THOMAS K. KAHN
	CLERK
D. C. Docket No. 06-20218-CR-PA	S
UNITED STATES OF AMERICA,	
]	Plaintiff-Appellee,
versus	
JORGE CABRERA,	
	Defendant-Appellant.
Appeal from the United States District of for the Southern District of Florida	
(June 30, 2008)	
Before ANDERSON, HULL and SILER,* Circuit Judges.	
PER CURIAM:	
	

^{*}Honorable Eugene Siler, Jr., United States Circuit Judge for the Sixth Circuit, sitting by designation.

After a jury trial, Jorge Cabrera appeals his two convictions and twenty-seven-month sentences for criminal offenses involving the unlawful wholesale distribution and transportation of prescription drugs in interstate commerce. After oral argument and review, we affirm Cabrera's convictions and sentences except for the restitution ordered to Medicaid.

I. BACKGROUND

A. Two-Count Superseding Indictment

Count One of the indictment charged that Cabrera and his codefendants

Omar Maceira and Victor Antonio Ramallo "willfully, that is, with the specific intent to further the objects of the conspiracy, and knowingly" conspired, in violation of 18 U.S.C. § 371, to commit two offenses: (1) violating the Food, Drug, and Cosmetic Act ("FDCA") by engaging in the wholesale distribution of prescription drugs in interstate commerce without a Florida license, with the intent to defraud or mislead, 21 U.S.C. §§ 331(t), 333(a)(2), 353(e)(2)(A); and (2) transporting goods stolen and taken by fraud in interstate commerce, 18 U.S.C. § 2314. Count Two charged them with the substantive FDCA offense that was the first object of the conspiracy count, i.e., the unlawful wholesale distribution of prescription drugs in interstate commerce without a Florida license, with the intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(t), 333(a)(2), and

353(e)(2)(A), and 18 U.S.C. § 2.

Codefendant Ramallo pled guilty before trial and was sentenced to thirtyfive months' imprisonment. Codefendant Maceira proceeded to trial with Cabrera.

Because Cabrera challenges the sufficiency of the evidence, we review certain trial evidence about (1) the regulation, manufacturing, and diversion of prescription drugs, and (2) Cabrera's specific conduct.¹

B. Prescription Drug Labeling, Pricing, and Diversion

At trial, Cesar Arias, a registered pharmacist and former drug inspector with the Florida Department of Health, described how prescription drugs are packaged and distributed. According to Arias, prescription drugs travel from manufacturers to wholesalers, who in turn distribute the drugs to pharmacies, hospitals, and physicians' offices. Wholesalers can buy prescription drugs from either the manufacturer or another licensed wholesaler. The pharmaceutical industry is heavily regulated.

For example, Florida law requires that "pedigree papers" accompany the drugs in almost every prescription drug transaction between wholesalers. Pedigree papers are documents that list each entity that has touched the drug with the date of

¹We review the sufficiency of the evidence <u>de novo</u>, recounting the evidence in the light most favorable to the government and accepting all reasonable inferences in favor of the verdict. <u>United States v. Klopf</u>, 423 F.3d 1228, 1236 (11th Cir. 2005).

sale, the name and strength of the drug, and the lot number of the batch. Pedigree papers are intended to protect the public's health by ensuring that prescription drugs travel through the proper channels of distribution.

Arias testified that every box or bottle of prescription drugs sold by a manufacturer has a manufacturer's label attached and either an "outsert" on the outside of the package or an "insert" inside the packaging. The outsert or insert explain, inter alia, how the product is meant to be used by medical professionals. The manufacturer's label lists, inter alia, the manufacturer's name and address, as well as the lot number, which allows for the tracking of the product and is used if the product is recalled. The bottles also have safety seals that prevent tampering. When a prescription drug is given to a patient by a pharmacy, the pharmacy typically transfers the drugs to a separate bottle with a patient label.

Arias also testified that the "diversion" of prescription drugs refers to the removing, and later returning, of prescription drugs from the ordinary chain of distribution. Sometimes drugs are stolen in shipment. Other times, "Medicaid diversion" involves acquiring drugs directly from a patient that are already paid for by Medicaid. The diverter typically pays ten to fifteen cents on the dollar for the Medicaid patient's drugs. The label containing the Medicaid patient's information is removed from the packaging with solvents such as lighter fluid. If the original

manufacturer's label is damaged during this process, counterfeit labels are made.

Diverters either obtain replacement outserts from pharmacies or make counterfeits.

After this process is completed, the drugs are reintroduced into the channels of distribution through profitable transactions with middlemen and wholesalers. This diversion allows for the prescriptions to be sold illegally below the average price charged by the manufacturer.

The wholesale acquisition cost ("WAC") is the average price a drug manufacturer charges wholesalers who buy the particular prescription drug. The average wholesale price ("AWP") is the average price a wholesaler in turn sells a particular drug, typically to pharmacies, and is usually twenty-five to thirty-five percent higher than the wholesaler's WAC. When wholesalers buy prescription drugs from other wholesalers, they typically pay one or two percent above WAC, but less than the AWP. Arias explained that it is a "red flag" and "highly suspicious" to regulators if prescription drugs are sold between wholesalers below WAC or below eighty percent of the AWP.

C. Conspiracy Investigation and March 22 Drug Transaction

Marc Reiche, a detective with the Miami-Dade County Sheriff's Department and a special task force agent with the Food and Drug Administration ("FDA"), was the undercover agent who posed as a buyer of prescription drugs from

Maceira, Ramallo, and Cabrera.²

On March 13, 2006, Reiche and Maceira met in a Publix grocery store parking lot. Reiche told Maceira that he was interested in purchasing large quantities of prescription drugs to ship to New York to sell. Maceira told Reiche that he could sell him drugs with a license and pedigree papers, but it would cost more, and that Reiche would have invoices for the drugs in case he encountered the police. Maceira assured Reiche that he checked all of the drugs and that they were clean with safety seals. Maceira told Reiche, "I get all the illegal stuff and I make it legal."

On March 14, 2006, Maceira and Reiche again met in the same Publix parking lot. Maceira showed Reiche a list of liquid prescription drugs that he had available. Maceira stated that he bought the drugs for approximately twenty-eight percent of the WAC and would sell them to Reiche at fifty-five percent of the WAC. Maceira gave Reiche a fax number to send his order. After this meeting, law enforcement agents faxed to Maceira an order to purchase five units each of the prescription drugs Procrit, Combivir, and Crixivan. In subsequent telephone conversations, Maceira set up a meeting between Reiche and codefendant Ramallo.

²A confidential informant advised law enforcement that a group of individuals was selling diverted prescription drugs and arranged a meeting between Reiche and codefendant Maceira.

On March 22, 2006, two meetings occurred. First, Reiche and Maceira met in a cafeteria parking lot and discussed the drug transaction. Later, Ramallo joined them, and Maceira left. Ramallo told Reiche that he was a doctor³ and had a pharmaceutical business. Ramallo and Reiche further discussed the details of their transaction. Ramallo indicated that he could provide prescription drugs with or without papers, but that they would be more expensive with papers. After the meeting, Ramallo and Reiche spoke by phone and arranged a meeting to conduct a prescription drug sale.

Ramallo and Reiche met again later that day in a parking lot behind a Hooters restaurant. Ramallo arrived at the meeting in a car driven by Cabrera, and they parked beside Reiche's car. Ramallo exited the car, walked around the back of the car, and met Cabrera on the driver's side. Cabrera removed a box from the back seat of the car, gave it to Ramallo, and returned to his car. Ramallo entered Reiche's car and handed him the box, which contained the requested quantities of the prescription drugs Procrit, Combivir, and Viracept, but not any invoices or pedigree papers for the drugs. Reiche gave Ramallo an envelope with \$9,800 in

³Reiche testified that Ramallo was not, in fact, a licensed physician in the United States.

⁴Cabrera's grandfather was also in the car with Cabrera and Ramallo.

⁵Ramallo substituted Viracept for the requested quantity of the drug Crixivan.

cash as payment, which was approximately sixty-two percent of the WAC and fifty-one percent of the AWP for the drugs. Detective Luis Hernandez, an FDA criminal investigator who observed this March 22 meeting, testified that Maceira arrived separately and that Ramallo and Maceira high-fived in celebration after the transaction.

Reiche also gave Ramallo a large order of drugs. From Reiche's car,

Ramallo called over to Cabrera and requested a drug inventory list from a laptop

computer bag. Cabrera exited his car and brought Ramallo the drug inventory list

from a computer bag. Ramallo later walked over to Cabrera's vehicle, obtained the

laptop computer bag from Cabrera, and produced another drug inventory list.

Ramallo and Reiche had subsequent telephone conversations regarding the new order. Reiche indicated to Ramallo that he wanted to see "the products." In one telephone conversation, Ramallo told Reiche that he would send Cabrera, whom Ramallo described as "my partner," to show Reiche what they had. During another phone call on March 28, 2006, Ramallo instructed Reiche on a meeting location. Reiche could hear Cabrera in the background assisting Ramallo with instructions.

D. March 28 Meeting at Cabrera's Warehouse

On March 28, 2006, Reiche met Ramallo and Cabrera at a warehouse in

Hialeah, Florida. Cabrera had signed a lease contract for the warehouse on behalf of Courier JC Corp.⁶ The parties stipulated that Courier JC Corp. was one of the five registered corporations for which Cabrera was an officer or registered agent, along with MCJF Corporation, Medi Medical Corporation, Shilo Corporation, and E & J Trading Corporation.⁷

Cabrera greeted Reiche when he first arrived at the warehouse, but acted nervous. Cabrera walked behind Reiche, told him where to sit, and watched him the entire time. Cabrera brought Reiche into the warehouse office, where Ramallo was talking on the phone. Cabrera, Ramallo, and Reiche went to the bay area of the warehouse where the prescription drugs were kept. Some drugs were displayed on a table and a hospital bed and others were stored in a refrigerator.

During the meeting, a man named Jorge Perez arrived at the warehouse with five more boxes of prescription drugs. Cabrera told Reiche that Perez was the guy who was bringing the drug Procrit. Cabrera said that Perez had twenty units of the Procrit, but Cabrera had told him to bring six of them.

⁶The lease contract was recovered from the warehouse.

⁷The stipulation indicated that Maceira was an officer or registered agent for three active corporations (Maceira Pet Shop, Inc.; O & N Medical and Diagnostic Center, Inc.; and Omnix Medical Center, Inc.) and that Ramallo was an officer or registered agent for seven active corporations (Health Research Services, Inc.; Mavic Quality Health, Inc.; Real Triana Bakery Corporation; Mavic Medical Center; Griffin Health Institute, LLC; All Technical Repairs, Inc.; and Professional Medical Lab, Inc.).

Ramallo and Cabrera began taking inventory of the drugs brought by Perez.

Ramallo noted that some of the drug labels were scratched. Cabrera was standing only five or six feet away when Ramallo said this. Ramallo also asked Reiche in Cabrera's presence if Reiche wanted to buy the drugs with or without papers.

Reiche questioned Ramallo and Cabrera as to the drug quantities available and, on multiple occasions, Cabrera answered Reiche's questions. Specifically, when Reiche asked about the availability of the prescription drug Kaletra, Cabrera told Reiche that, "I had exactly thirty-six (36), and I gave them to somebody" and later said, "We have ways of ordering it."

While Cabrera was taking inventory of the newly arrived drugs, Reiche commented, in reference to those drugs, "Well, that's stolen." Ramallo responded, "Yes, it comes like that. I don't really care how they bring it, anyway." Reiche testified that he noticed that the drugs that were unloaded had Federal Express shipping labels indicating that they were shipped from Pfizer to a Cardinal distributor in Greensboro, North Carolina. Ramallo removed the shipping labels from the boxes and told someone to throw them outside. Cabrera was taking inventory of the drugs in the boxes when Ramallo said this. Ramallo indicated that he would set aside the five new boxes of drugs for Reiche.

⁸Reiche indicated that Cabrera's statement, which was in Spanish, could have been interpreted as either "I" or "we."

With Cabrera present, Reiche later asked Ramallo, "[W]here do those come from? Stolen?" Ramallo responded, "I don't know. . . . I have never asked them, pal. You know what I'm saying?" Later, when Cabrera was apparently no longer present, Reiche asked how much it would cost for all of the drugs he wanted. Ramallo responded that he and Cabrera would "both sit for a bit" and then Ramallo would give Reiche a total. Ramallo gave Reiche a copy of a new drug inventory list that Cabrera had made reflecting the drugs that had just arrived.

E. March 29 Meetings, Drug Transaction, and Arrests

On March 29, 2006, Reiche met with Ramallo again in the same parking lot behind a Hooter's restaurant. Ramallo was driving Cabrera's car, but Cabrera was not present. In the course of telling Reiche a story regarding another prescription drug transaction, Ramallo admitted to Reiche that he dealt in stolen drugs.

Ramallo and Reiche discussed the deal for the drugs Reiche had previously requested, and Ramallo told him the price would be \$223,411.47.

After the March 29 meeting, Reiche called Ramallo, but Cabrera answered Ramallo's phone. Cabrera told Reiche that he was heading towards where Ramallo was and would be there in fifteen minutes. Cabrera also said that Ramallo told him to tell Reiche that the other drugs that he wanted would be ready that afternoon. When Reiche asked about the final price, Cabrera said he did not know so he

would talk to Ramallo and call him back in fifteen minutes.

Later that day on March 29, 2006, Reiche again met with Ramallo and Cabrera at Cabrera's warehouse. Reiche noted that the drugs that were previously on the table and hospital bed were not there. Cabrera exited the warehouse, removed a box containing prescription drugs from his vehicle parked outside, and brought it into the warehouse. Cabrera started to take inventory of the prescription drugs in the box in the bay area of the warehouse. Ramallo and Reiche exited the warehouse and walked to Reiche's car to retrieve the checks to pay for the drugs. Reiche then gave the takedown signal and law enforcement moved in and apprehended Ramallo and Cabrera. Cabrera was inside the warehouse when he was arrested.

Following the arrests, law enforcement searched the warehouse and recovered prescription drugs, patient records, and medical equipment. The box Cabrera retrieved from the car contained a variety of prescription drugs. Jacinta Batson, a forensic chemist with the FDA Forensic Chemistry Center, testified that she tested samples of drugs seized in this case and that they revealed signs of

⁹Gabriel Rodriguez, a detective with the Miami-Dade Police Department who provided security for Reiche at the warehouse on March 29, 2006, testified that the "subjects," one of whom was Cabrera, arrived a few minutes after Reiche. They were inside the warehouse for approximately 15 to 20 minutes. Cabrera then went outside, removed a box from the back of his car, and returned to the warehouse with the box. A few minutes later, Reiche and Ramallo exited the warehouse, and Reiche gave the arrest signal.

counterfeiting and diversion. Specifically, Batson testified that the tests revealed that the drugs were authentic, but that the adhesive used to attach the outserts on some containers was different from that used by the manufacturer, the outserts and labels on many of the containers were not authentic, and the bottles and boxes of some drugs contained blotches that were consistent with diverted products.

The parties stipulated that a November 10, 2005 Federal Express shipment of thirteen pallets of prescription drugs from Pfizer in New Jersey to a Cardinal health facility in Greensboro, North Carolina was stolen near Harrisburg,

Pennsylvania. The drugs recovered in Cabrera's warehouse that were brought by

Perez on March 22 had the same lot numbers as the stolen drugs. The stipulation listed nineteen drugs involved in the case that had traveled in interstate commerce.

The government also presented testimony from Valeria Williams from the Florida Department of Health that there were no Florida licenses to engage in wholesale distribution of prescription drugs issued to Cabrera, Maceira, or Ramallo or any of the corporations for which they were officers or registered agents. Williams further testified that no one had a license for wholesale distribution of prescription drugs at the address of Cabrera's warehouse.

Cabrera did not testify, but introduced one exhibit in his defense that showed that Ramallo's driver's license was suspended on March 7, 2006.

F. Jury Instructions

Before trial, the government submitted proposed jury instructions and a supporting memorandum that argued, inter alia, that the district court should depart from the Eleventh Circuit Pattern Jury Instruction defining "willfully" because it required the jury to find that the defendant acted "with bad purpose either to disobey or disregard the law." The government's memorandum argued that the pattern instruction erred in making knowledge of the law an element of all conspiracy prosecutions, regardless of whether such knowledge would be required to prove the charged object as a substantive offense. The government contended that neither of the charged object offenses in this case required the government to prove willfulness or knowledge of the law as an element.

The district court rejected the government's proposed change to the pattern jury instruction because the case involved a specific intent crime as an object of the conspiracy. However, the district court agreed with the government that lack of knowledge of the law was not a defense and informed the parties that it would add language from United States v. Starks, 157 F.3d 833 (11th Cir. 1998), to the pattern jury instruction stating that a person need not be aware of the specific law or rule that his conduct may be violating, but he must act with the intent to do something that is unlawful.

Cabrera and codefendant Maceira objected to this change to the jury instruction and requested to reserve argument on the instruction because the evidence in this case was materially different from Starks. They contended that Starks involved kickbacks, which are malum per se because everyone knows they are illegal, whereas this case involved a malum prohibitum offense in a complicated regulatory field where it was not common knowledge that the defendants were acting unlawfully.

Cabrera renewed this objection when the district court returned to the discussion of the jury instruction at trial. The government responded that <u>Starks</u> concerned a conspiracy to violate an anti-kickback statute that had a willfulness requirement, whereas the underlying statute here did not.

The district court overruled Cabrera's objection to the jury instruction. The district court stated that Cabrera's argument "defies common sense" because it would not make sense for the manufacturing and distribution of prescription drugs from a manufacturer to be controlled, but for there not to be any regulation of the chain of custody from the manufacturer to the pharmacy. The district court stated that it would follow Starks, because, like kickbacks, everyone knows that prescription drugs are highly regulated and can be dispensed only with a prescription. The district court stated that prescription drugs were an industry

where "it's common sense that before anyone gets engaged in it, that you go and find out the terms of what you're dealing with" and that you "make sure that you've crossed your T's and dotted your I's before you engage in this type of business." The district court clarified that "[y]ou don't have to know the specifics of the statute" at issue.

At the end of the trial, the district court instructed the jury on the four elements that the government had to prove to establish a conspiracy violation, which included "that the defendant, knowing the unlawful purpose of the plan, willfully joined in it." The district court further explained to the jury that:

The word "willfully," as that term is used in the Indictment or in these instructions, means that the act was done voluntarily and purposefully, and with the intent to do something the law forbids; that is, with the bad purpose to disobey or to disregard the law. A person need not be aware of the specific law or rule that his conduct may be violating. But he must act with the intent to do something that is unlawful.

The district court also instructed the jury that the FDCA violation that was charged as an object of the conspiracy and as a separate substantive offense required the government to prove "that the defendant acted knowingly and with the intent to defraud or mislead." The district court explained to the jury that "[t]o act with intent to defraud' means to act knowingly with the specific intent to deceive or cheat one, ordinarily for the purpose of causing some financial loss to another or

bringing about some financial gain to oneself."

G. Jury Verdict

The district court denied Cabrera's motions for a judgment of acquittal at the close of the government's case and at the end of the trial. The jury convicted Cabrera on both counts of the indictment and specifically found that Cabrera had conspired to achieve both objects of the conspiracy charged in Count One.

H. Sentencing

The Presentence Investigation Report ("PSI") assigned a base offense level of six, pursuant to U.S.S.G. § 2B1.1(a)(2), and applied a fourteen-level enhancement, pursuant to § 2B1.1(b)(1)(H), based on the loss amount of \$403,248.51.¹⁰ This loss amount included: (1) a WAC of \$15,220.32 for the stolen drug shipment from Pfizer; and (2) \$388,028.19 for the remaining drugs involved in the conspiracy, which represented the amount Medicaid would have paid for the drugs because they were likely purchased from Medicaid recipients.¹¹ The PSI did not recommend a role reduction because Cabrera worked closely with Ramallo and

¹⁰The PSI also initially applied a two-level enhancement, pursuant to § 2B1.1(b)(4), because Cabrera was a person in the business of receiving and selling stolen property, but later eliminated this enhancement.

¹¹On appeal, Cabrera does not challenge the calculation of the loss amount under the guidelines. Rather, as noted later, Cabrera contends only that the loss amount overstated the seriousness of the offense and thus warranted a downward departure or a downward variance from the advisory guidelines range.

was more familiar with the drug inventory than Ramallo. Based on a total offense level of twenty and a criminal history category of I, Cabrera's advisory guidelines range was thirty-three to forty-one months' imprisonment. The PSI also indicated that Cabrera owed \$15,220.32 in restitution to Pfizer and \$388,028.19 in restitution to the Center for Medicare/Medicaid Services.

Cabrera objected to the PSI's failure to recommend a role reduction and to its loss amount calculation on several grounds. He also requested a downward departure or sentence variance because the offense was non-violent and aberrant behavior for him, his involvement was minimal, and the loss amount overstated his culpability.

At sentencing, the district court used solely the WAC (and not what Medicaid likely would have paid) to calculate the loss amount for all of the drugs involved in the conspiracy, which changed the loss amount to \$379,085.16 and thus decreased the loss-amount enhancement from fourteen to twelve levels. This changed Cabrera's offense level to eighteen and his advisory guidelines range to twenty-seven to thirty-three months' imprisonment.

The district court denied Cabrera's requests for a role reduction or a downward departure. The district court explained that Cabrera knew what he was doing because he had been in the business world and in the Medicare field, that he

had provided important infrastructure to the conspiracy, and that the circumstances were not extraordinary because there was no indication of remorse or acceptance of responsibility. The district court found that Cabrera was more than just a landlord of the warehouse because Cabrera (1) was more familiar with the drug inventory than Ramallo, (2) took careful inventory of the drugs in the warehouse, (3) handled deliveries, (4) was involved in setting prices, and (5) participated in the aborted March 29 sale by bringing prescription drugs worth nearly \$400,000 from his car into the warehouse.

The district court also declined to vary downward from the advisory guidelines range. The court stated that it realized this was Cabrera's first offense, but it had to consider all of the 18 U.S.C. § 3553(a) factors, including the need to avoid unwarranted sentencing disparities. The district court opined that diversion of pharmaceuticals was a serious matter with serious health consequences. Stating that it had considered the statements of the parties, the PSI, the advisory guidelines range, and the statutory factors, the district court sentenced Cabrera to twenty-seven months' imprisonment on both counts, to be served concurrently. The district court ordered Cabrera to pay \$379,085.16 in restitution, which consisted of \$15,220.32 to Pfizer and the remaining \$363,864.84 to Medicaid. After the sentence was imposed, Cabrera renewed his earlier objections.

II. DISCUSSION

On appeal, Cabrera raises the following arguments: (1) the district court erred in failing to instruct the jury that it had to find that Cabrera acted with knowledge of the specific law he was violating and, by doing so, constructively amended the indictment; (2) the evidence was insufficient to convict Cabrera of the two charges; (3) the district court erred in denying Cabrera a downward departure on the grounds that the loss amount overstated the seriousness of the offense; (4) the district court erred in denying Cabrera a mitigating role

¹²We review <u>de novo</u> the legal correctness of a jury instruction, but give the district courts broad discretion in phrasing jury instructions, so long as the charge as a whole accurately reflects the law and the facts. <u>United States v. Mintmire</u>, 507 F.3d 1273, 1292-93 (11th Cir. 2007). We will not reverse a conviction based on a jury instruction unless "the issues of law were presented inaccurately, or the charge improperly guided the jury in such a substantial way as to violate due process." <u>Id.</u> at 1293 (quoting <u>United States v. Prather</u>, 205 F.3d 1265, 1270 (11th Cir. 2000)).

A jury instruction that constructively amends an indictment is normally <u>per se</u> reversible error because such an amendment violates a defendant's Fifth Amendment right to be charged by a grand jury indictment. <u>United States v. Keller</u>, 916 F.2d 628, 636 (11th Cir. 1990). "In evaluating whether the indictment was constructively amended, we review the district court's jury instructions . . . 'in context' to determine whether an expansion of the indictment occurred either literally or in effect." <u>United States v. Castro</u>, 89 F.3d 1443, 1450 (11th Cir. 1996).

¹³In reviewing loss calculations, which involve both legal and factual issues, we review a district court's factual findings for clear error and its application of the guidelines <u>de novo</u>. <u>United States v. Gupta</u>, 463 F.3d 1182, 1199 (11th Cir. 2006), <u>cert. denied</u>, ___ U.S. ___, 127 S. Ct. 2446 (2007). We lack jurisdiction to review a district court's discretionary decision not to apply a downward departure, but we review <u>de novo</u> whether a district court mistakenly believed that it lacked the authority to depart. <u>United States v. Pressley</u>, 345 F.3d 1205, 1209 (11th Cir. 2003).

reduction;¹⁴ (5) the district court applied presumptive weight to the guidelines and imposed a substantively unreasonable sentence;¹⁵ and (6) the district court erred in its restitution order because the government failed to prove that anyone in fact suffered that amount of loss and because it was imposed based on judicial fact findings in violation of Cabrera's Fifth and Sixth Amendment rights under <u>United States v. Booker</u>, 543 U.S. 220, 125 S. Ct. 738 (2005).¹⁶ After thorough review, we affirm Cabrera's convictions and twenty-seven-month sentences, except for the restitution ordered to Medicaid. Only three of these six issues—the jury instructions, sufficiency of the evidence, and restitution award—warrant further discussion.

A. Jury Instructions

A conviction for criminal conspiracy requires proof of at least the degree of

¹⁴A district court's determination of a defendant's role in an offense is a finding of fact that we review for clear error. <u>United States v. De Varon</u>, 175 F.3d 930, 937-38 (11th Cir. 1999) (en banc).

¹⁵We review sentences under a deferential abuse-of-discretion standard in which we consider (1) whether the district court committed any significant procedural error at sentencing, and (2) whether the ultimate sentence imposed is substantively reasonable in light of the totality of the circumstances. See United States v. Pugh, 515 F.3d 1179, 1189-90 (11th Cir. 2008).

¹⁶We review <u>de novo</u> the legality of a restitution order and review a factual finding regarding the specific restitution amount for clear error. <u>United States v. Foley</u>, 508 F.3d 627, 632 (11th Cir. 2007).

Criminal intent required for conviction of the underlying substantive offense. United States v. Simmons, 725 F.2d 641, 643 (11th Cir. 1984). The first object of the conspiracy in Count One and the substantive offense in Count Two were the same: that Cabrera violated 21 U.S.C. §§ 331(t), 333(a)(2), and 353(e)(2)(A) of the FDCA.

More specifically, § 331(t) prohibits the distribution of drugs in violation of 21 U.S.C. § 353(e). 21 U.S.C. § 331(t). In turn, § 353(e)(2)(A) restricts the wholesale distribution in interstate commerce of drugs in a state without being licensed to do so by that state. 21 U.S.C. § 353(e)(2)(A). And § 333(a)(2) makes a violation of § 331 a felony when a defendant acts "with the intent to defraud or mislead." 21 U.S.C. § 333(a)(2); United States v. Bradshaw, 840 F.2d 871, 872 (11th Cir. 1988). Thus, to prove the first object of the conspiracy and the substantive offense, the government had to show that Cabrera conspired to engage in the wholesale distribution in interstate commerce of drugs without being licensed to do so, with the intent to defraud or mislead.

Cabrera contends that the government was also required to prove that he

¹⁷On appeal, Cabrera does not challenge the jury instructions as to the second object of the conspiracy, violating 18 U.S.C. § 2314, or as to Count Two of the indictment.

¹⁸Violating § 331, irrespective of any particular <u>mens rea</u>, is a misdemeanor. <u>See</u> 21 U.S.C. § 333(a)(1) (providing that any person who violates 21 U.S.C. § 331 shall be imprisoned not more than a year); <u>United States v. Bradshaw</u>, 840 F.2d 871, 872 (11th Cir. 1988) (stating that a violation of 21 U.S.C. § 331 is a "misdemeanor[] regardless of the violator's intent.").

FDCA violation was a <u>malum prohibitum</u> offense in a complicated regulatory field that would not be obviously illegal. Cabrera argues that the district court erred in instructing the jury that the term "willfully" means that a defendant "must act with the intent to do something that is unlawful," but that "[a] person need not be aware of the specific law or rule that his conduct may be violating."

This Court addressed and rejected a similar mens rea argument in Starks.

The defendants in Starks were charged with and convicted of violating an anti-kickback provision of the Social Security Act, which prohibited "knowingly and willfully solicit[ing] or receiv[ing] any remuneration" for referrals for services covered by the federal government. Starks, 157 F.3d at 837. The district court in Starks instructed the jury that the term willfully "means the act was committed voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law." Id. at 838.

In affirming in Starks, this Court discussed the jury instruction in Bryan v. United States, 524 U.S. 184, 118 S. Ct. 1939 (1998), about "willfully" dealing in firearms without a federal license under 18 U.S.C. § 924(a)(1)(D). The Supreme Court in Bryan concluded that "a jury may find a defendant guilty of violating a statute employing the word 'willfully' if it believes 'that the defendant acted with

an evil-meaning mind, that is to say, that he acted with knowledge that his conduct was unlawful." Starks, 157 F.3d at 838 (quoting Bryan, 524 U.S. at 193, 118 S. Ct. at 1946). Bryan distinguished tax or financial cases that "involved highly technical statutes that presented the danger of ensnaring individuals engaged in apparently innocent conduct." Id. (quoting Bryan, 524 U.S. at 194, 118 S. Ct. at 1946-47). In contrast, Bryan determined that "[t]he danger of convicting individuals engaged in apparently innocent activity that motivated our decisions in the tax cases . . . is not present here because the jury found that this petitioner knew that his conduct was unlawful." Bryan, 524 U.S. at 195, 118 S. Ct. at 1947. The Supreme Court in Bryan concluded that "the willfulness requirement of § 924(a)(1)(D) does not carve out an exception to the traditional rule that ignorance of the law is no excuse; knowledge that the conduct is unlawful is all that is required." Id. at 196, 118 S. Ct. at 1947.

Similarly to <u>Bryan</u>, this Court in <u>Starks</u> concluded that the anti-kickback statute at issue "is not a highly technical tax or financial regulation that poses a danger of ensnaring persons engaged in apparently innocent conduct." <u>Id. Starks</u> stated that "the giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal" and that "such kickbacks are more clearly malum in se, rather than malum prohibitum." Id. Thus, there was no error

in the district court's instruction. Id. at 839.

In light of <u>Starks</u> and <u>Bryan</u>, we find no error in the district court's jury instruction here on the term "willfully." Similar to the willful dealing in firearms without a license discussed in <u>Bryan</u>, the FDCA violation charged here of wholesale distribution of prescription drugs without a license is not the type of law that poses a danger of ensnaring potentially innocent conduct. As the district court here noted, it is common knowledge that prescription drugs, similar to firearms, are highly regulated in order to ensure the public's safety.

Furthermore, the FDCA substantive crime at issue here does not contain an explicit requirement of a willful violation like those at issue in <u>Starks</u> and <u>Bryan</u>.

21 U.S.C. §§ 331(t), 333(a)(2), 353(e)(2)(A). Instead, it requires the heightened intent that Cabrera acted "with the intent to defraud or mislead." 21 U.S.C.

§ 333(a)(2). The district court defined the term "willfully" for the jury, in part, because the indictment charged that Cabrera willfully entered the conspiracy, not because the FDCA offense contains a willfulness requirement.

Cabrera also has provided no support for his argument that the district court should have read into the FDCA a requirement that he acted with knowledge of the specific provision of the FDCA he was violating. The cases from other circuits cited by Cabrera acknowledge only that the "intent to defraud or mislead" required

for a felony violation must be connected to the charged substantive violation and that there must be knowledge of the essential nature of the fraud. See United

States v. Geborde, 278 F.3d 926, 930 (9th Cir. 2002); United States v. Arlen, 947

F.2d 139, 143 (5th Cir. 1991); United States v. Mitcheltree, 940 F.2d 1329, 134950 (10th Cir. 1991); United States v. Hiland, 909 F.2d 1114, 1128 (8th Cir. 1990).

But those cases do not state that knowledge of the specific FDCA law being violated is required for a felony violation of the FDCA. To the contrary, the

Eighth Circuit's decision in Hiland states that "there is nothing in § 333(a)(2), or elsewhere in the FDCA, that evidences a congressional intent to create such an exception to 'the general rule that ignorance of the law is no excuse.'" Hiland, 909

F.2d at 1129 n.21 (quoting United States v. Int'l Minerals & Chem. Corp., 402

U.S. 558, 563, 91 S. Ct. 1697, 1701 (1971)).

Accordingly, the district court properly determined that the FDCA violation at issue here did not carve out an exception to the general rule that ignorance of the law is not an excuse and, as in <u>Starks</u> and <u>Bryan</u>, the district court properly instructed the jury that the charged offenses required that Cabrera "need not be aware of the specific law or rule that his conduct may be violating" but "must act with the intent to do something that is unlawful." Thus, we discern no error in the

district court's jury instruction defining the term "willfully." ¹⁹

B. Sufficiency of the Evidence

Cabrera also argues that the evidence was insufficient to show that he knowingly and willfully participated in the conspiracy or that he knowingly committed the substantive FDCA offense. Cabrera notes that Ramallo held himself out as a doctor and contends that he only served as a chauffeur for Ramallo on a few occasions and carried out his duties as a warehouse owner.

After thorough review of the record, we conclude there is ample evidence to support the jury's verdict convicting Cabrera on both counts. Viewing the evidence in the light most favorable to the government, the evidence of Cabrera's active participation in both the March 22 prescription drug sale and the planned March 29 prescription drug sale and his extensive knowledge and involvement with the prescription drug inventory, including the sources of those drugs, is more than sufficient to support a reasonable jury inference that Cabrera had the required mens rea to commit both offenses.

C. Restitution

The PSI stated that, other than the stolen shipment of drugs from Pfizer,

¹⁹Because we find no error in the district court's jury instruction, we also reject Cabrera's argument that the district court's jury instruction constituted a constructive amendment of the indictment.

"[t]he remaining drugs in this conspiracy were diverted drugs, purchased from retail pharmacies, usually by Medicaid." The PSI calculated the price that Medicaid would have paid for these diverted drugs and recommended that the district court order restitution to the Center for Medicare/Medicaid Services.

At sentencing, the government stated that it knew that Pfizer was the source of the small stolen shipment, but conceded that it did not know the source of the other drugs involved in the conspiracy. The government admitted that as to "[t]he remainder of the drugs, there would be no way to determine at what point that they were either stolen or obtained by fraud, although the evidence indicated, at least for a large portion of them, that they appeared to be diverted." Nevertheless, the district court ordered that Cabrera pay \$363,864.84 in restitution to Medicaid.

The government bears the burden of proving the victim and the restitution owed by a preponderance of the evidence. 18 U.S.C. § 3664(e). On appeal, the government concedes that, other than Pfizer, it failed to meet its burden of proof of an identifiable victim to whom restitution could be awarded. The government admits that the evidence presented at trial that Medicaid fraud is the most common form of prescription drug diversion was insufficient to establish that Medicaid was the actual victim in this case. We agree and thus vacate the district court's award of \$363,864.84 in restitution to Medicaid.

III. CONCLUSION

We vacate the district court's restitution award to Medicaid. However, we affirm Cabrera's convictions and twenty-seven-month sentences in all other respects.

AFFIRMED IN PART; VACATED IN PART.